

## REMARKS

Claims 1-19 are pending in the subject application. Claim 19 has been introduced and claims 1-3, 10, 12, 15, 16 and 18 have been amended to correct minor typographical errors pointed out by the Examiner and to more particularly point out the claimed invention. Support for the amendment to claim 16 and new claim 19 can be found throughout the specification (see, for example page 41, lines 13-17). No new matter has been introduced by the instant amendment. Reconsideration of the application in view of the remarks which follow is respectfully requested.

Enclosed is a declaration under Rule 1.131 executed by each of the named inventors which provides that the purified leuporelin compositions provided by claims 16, 17, and 19 were in possession of the inventors before December 18, 1998.

The specification has been amended to delete recitations of "etc." and to add hyphens between the stereodesignation "D" and the amino acid. Thus, Applicants request withdrawal of the objections to the specification.

Claims 1-16, and 18 were rejected under 35 U.S.C. §112, second paragraph, as being allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims, as amended, are fully compliant with the requirements of §112, including the requirements of §112, second paragraph. Thus, applicants request withdrawal of the rejections and reconsideration of the claims.

Claims 16 and 17 were rejected under 35 U.S.C. §102(e) as being allegedly anticipated by Hutchinson (U.S. Patent 5,889,110).

The office action has alleged that claims 1, 4, and 45 of the Hutchison patent discloses a purified leuporelin or leuoporelin acetate preparation.

Applicants traverse the rejection.

Hutchison neither teaches nor suggests purified leuporelin compositions having less than 1% impurity content. Moreover, Hutchison neither teaches nor suggests how to make or use any purified leuporelin compositions.

The Office Action appears to rely upon the recitation of leuporelin as a possible one of several peptide drugs incorporated into an injectable composition provided by claim 4 and the injectable microparticle composition of claim 45 which comprises a peptide drug which may be selected to be leuporelin.

Notwithstanding the improper reliance upon claim language for establishing a §102 rejection, Hutchison neither discloses nor suggests a level of purity for any of the basic peptide drugs recited therein and more particularly, Hutchison does not teach or suggest purified leuporelin compositions having less than about 1% total impurity content. Moreover, Hutchison neither teaches nor suggests purified leuporelin compositions in which the the content of 5-oxo-Pro-D-His-Trp-Ser-Tyr-D-Leu-Leu-Arg-Pro-NH-CH<sub>2</sub>-CH<sub>3</sub> or a salt thereof is about 0.3% or less, or purified leuporelin compositions in which the impurities are racemic isomers of the LH-RH derivatives and/or highly polar related substances.

Thus, claims 16, 17 and 19, which provide purified leuporelin having less than 1 % total impurity content, is not anticipated by the Hutchinson patent.

Claims 16 and 17 were rejected under 35 U.S.C. §102(e) as being allegedly anticipated by Hatanaka (U.S. Patent 6,211,333).

Applicants submit herewith a Rule 131 Declaration that effectively antedates the §102(e) date of U.S. Patent 6,211,333 issued to Hatanaka. Thus, Hatanaka is not available as prior art under 35 U.S.C. §102(e) or 35 U.S.C. §103(a) against the claims of the instant application.

Accordingly, applicants request withdrawal of the rejections and allowance of the claims.

Reconsideration and allowance of claims 1-19 is respectfully requested in view of the foregoing discussion. This case is believed to be in condition for immediate allowance.

If for any reason a fee is required, a fee paid is inadequate or credit is owed for any excess fee paid, you are hereby authorized and requested to charge Deposit Account No. 04-1105.

Should the Examiner wish to discuss any of the amendments and/or remarks made herein, the undersigned attorney would appreciate the opportunity to do so.

Respectfully submitted,



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Stephana E. Patton, Ph.D. (Reg. No. 50,373)  
John B. Alexander, Ph.D. (Reg. No. 48,399)  
EDWARDS & ANGELL, LLP  
P.O. Box 55874  
Boston, MA 02205  
Tel. No. (617) 439-4444